IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jackson, et al.		
Application No.: 10/828,394		
Filed: 4/19/2004	Group Art Unit:	1635
Title: Method for Treatment of Cancerous Angiogenic Disorders	Examiner:	Tracy Ann Vivlemore
	Confirmation No.:	5855
Attorney Docket No.: UBC.P-033		

BRIEF FOR APPELLANT

This brief is filed in support of Applicants' Appeal from the final rejection mailed 2/28/2006. Consideration of the application and reversal of the rejections are respectfully urged.

Real Party in Interest

The real party in interest is The University of British Columbia.

Related Appeals and Interferences

With respect to the written description issue, this appeal is related to the appeal of commonly assigned application serial no. 09/619,908. The decision of the Board of Appeals in this case is attached in the Appendix. An appeal of this decision is being pursued with the Court of Appeals for the Federal Circuit. However, the decision of the Board supports the argument as set forth below, and is not at issue in the further appeal.

Status of Claims

Claims 6-8 are pending and rejected. Claims 9 and 10 are withdrawn. Claims 1-5 have been canceled. No other claims have been presented in this application.

Status of Amendments

The amendment after final rejection filed March 28, 2006 has been entered.

Summary of Claimed Subject Matter

This application relates to a method for reducing angiogenesis in a cancerous angiogenesis-related disease, comprising treating cells of the cancer with amount of a therapeutic oligonucleotide composition effective to reduce the effective amount of clusterin in the cells, and thereby to reduce the occurrence of angiogenesis. (Claim 6). The claimed method is based on the finding of the inventors that reduction in levels of clusterin leads to a reduction in angiogenesis. (Page 1, lines 11-12). The oligonucleotide therapeutic agent is suitably complementary to the sequence of human clusterin (claim 7). The sequence of human clusterin is presented in the application as Seq. ID No.: 1. (Page 4, lines 5-8). Specific examples of oligonucleotide therapeutics are provided in the specification in the form of antisense (claims 7 and 8, SEQ ID Nos. 2-15) and RNAi sequences (withdrawn claims 9 and 10, SEQ ID Nos.: 16-23).

Grounds of Rejection to be reviewed on Appeal

Claim 6 is rejected under 35 USC § 112, first paragraph, as lacking written description.

Claims 6 and 7 are rejected as anticipated by US Patent No. 6,383,808 of Monia et al. ("Monia")

Claims 6-8 are rejected as anticipated by US Patent No. 6,900,187 of Gleave et al. ("Gleave '187")

Claims 6-8 are rejected as anticipated by US Publication 2003/0158130 of Gleave et al. ("Gleave 2003")

Claims 6 and 7 are provisionally rejected for obviousness-type double patenting over claims of copending application 10/646,436.

Argument

1. *The Written Description Rejection*

Claim 6, which does not recite specific sequences for the therapeutic target is rejected under 35 USC § 112, first paragraph, for lack of written description. The Examiner argues in the advisory action mailed April 25, 2006 that the rejection is maintained because

> claim 6 encompasses the use of oligonucleotides effective to reduce the amount of clusterin in species for whom the sequence of clusterin is yet to be discovered... The Examiner recognizes that the invention is not the clusterin inhibitor, but because the invention requires the use of such inhibitors a description of the structure of the inhibitor is necessary.

Applicants submit that this is not a valid basis for a rejection based on written description in this instance, and that the rejection should therefore be reversed.

The written description rejection in this case is of the new, second type, which has recently emerged in court decisions, rather than the older "new matter" type of rejection. This second type of rejection has recently been described by the Court of Appeals for the Federal Circuit as follows:

> The second application of the written description requirement is reflected in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). There, this court invoked the written description requirement in a case without priority issues.
>
> * * *
>
> More recently, in *Enzo Biochem*, we clarified that *Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure. Amgen, 314 F.3d at 1332.
>
> The test for compliance with §112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing. See *Vas-Cath*, 935 F.2d at 1561 ("Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be

> encompassed within his original creation"). The possession test requires assessment from the viewpoint of one of skill in the art. Id. at 1563-64 ("the applicant must ... convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention") (emphasis in original); *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'") (citation omitted).

The focus of the written description requirement is therefore plainly on the **invention**, that is the contribution made by the inventors. The new face of the written description requirement is not intended to limit claims to the specific examples of the invention set forth in the specification, or to prevent claim scope that includes embodiments or improvements that may be developed later by the inventors or others. Indeed, earlier case law makes this very clear.

Consideration of *In re Fuetterer*, 319 F.2d 259, 138 USPQ 217 (CCPA 1963) demonstrates the importance of focusing on the invention as claimed. The claims in Fuetterer referred to a rubber stock composition useful in producing tire treads and included a functional recitation of "an inorganic salt capable" of maintaining an homogeneous distribution of another component in the composition. The disclosure listed the function desired and four members of the class having that function. The CCPA found that this claim met the requirements of 35 U.S.C. § 112, first paragraph, stating that:

> Appellant's invention is the combination claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure.

319 F.2d at 265, 138 USPQ at 223.

In this case, the invention is based on the discovery by the inventors that reducing the expression of clusterin also reduces angiogenesis. As the Examiner has recognized, Applicants' invention is not antisense technology *per se*. It is also not the identification of clusterin, nor any and all inhibitors of clusterin expression. What Applicants' claim as their invention is a method for reducing angiogenesis by reducing clusterin expression via an oligonucleotide therapeutic agent. The Examiner is arguing is that to protect the full scope of their invention and prevent copying of Applicants' discovery in other species besides humans, Applicants are required to discover every sequence for which they want protection. This is not consistent with established law.

Also of relevance to the written description issue are several other recent cases of the Court of Appeals for the Federal Circuit in which the importance of looking at the claimed invention is demonstrated. *Capon v. Eshhar*, 76 USPQ 2d 1078 (Fed. Cir. 2005) is based on an interference proceeding in which both parties claimed chimeric genes comprising a gene segment encoding a single-chain (scFv) antibody, and a second gene encoding a cytoplasmic signaling domain. Expression of a chimeric gene resulted in cells that expressed a cell surface marker that produced cell signaling in response to binding of an antigen to the scFV antibody. The Board of Patent and Appeals and Interferences had held that both specifications were lacking in written description because of a limited number of examples, and the absence of a complete sequence of at least one chimeric gene within the scope of the claims. In vacating the decision of the Board of Appeals holding, the Federal Circuit observed that "the 'written description' requirement must be applied in the context of the particular invention." 76 USPQ2d at 1084-5. More recently, in *Invitrogen Corp. v. Clontech Laboratories Inc.*, 77 USPQ2d 1161 (Fed. Cir. 2005) upheld a finding on motion for summary judgment that a specification provided adequate written description for modified reverse transcriptase (RT) based on a finding of starting sequences in the art in addition to those in the specification.

In *Invitrogen* the claims found to have adequate written description are not limited to RTs where the basic sequence was already known. Similarly, the claims at issue in *Capon* were not

limited so as to exclude later developed single chain antibodies or later discovered or characterized signaling domains. Thus, the Examiner's argument is inconsistent with these decisions. Thus, Applicants submit that the written description rejection of claim 6 should be withdrawn.

The Examiner's position is not consistent with the Written Description Guidelines published by the USPTO, and particularly Example 15 thereof. The Examiner's rejection is also inconsistent with the decision on appeal of the related case cited above. In that decision, the Board of Appeals reversed a rejection much like this one, stating that:

> Here, the specification sets forth the sequences of DNA molecules encoding the mouse and human IGFBP-5s, as well as a number of antisense sequences targeting specific regions of the mouse and human IGFBP-5 DNAs. The examiner's rationale would seem to limit the claimed genus to only those antisense oligonucleotides explicitly recited, without explaining why one skilled in the art would not have expected the mouse and human DNAs to be representative of, or have considerable structural similarity to, DNA encoding IGFBP-5 in other mammals. Again, it is the examiner's "initial burden [to] present[ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (*Wertheim*, 541 F.2d at 263,191 USPQ at 97). We find that the examiner has not done so.

Page 12. The same is true here, and the rejection for lack of written description should be reversed.

2. *The Anticipation Rejections*

The rejections under 35 USC § 102 in this case share as a common thread the fact that the Examiner is focusing on just one part of the claim, and ignoring the preamble of the method claim that defines what the invention is about. The Court of Appeals for the Federal Circuit has observed that

> "In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1784 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir.

> 1999)). "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995).

Eaton Corp. v. Rockwell International Corp., 66 USPQ2d 1271 (Fed. Cir. 2003). In the present case, the preamble cannot be deemed superfluous, since it says what is being accomplished by the method, namely a reduction in angiogenesis in the a cancerous angiogenesis related disease, and the claim without these words is meaningless. Indeed, the notion that preamble language is generally meaningless in method claims would render second use method claims impossible.

The importance of the preamble in method claims of this type is reflected in *Jansen v. Rexall Sundown, Inc.*, 68 USPQ 2d 1154 (Fed. Cir. 2003). In that case, the claims at issue were directed to "a method of treating or preventing macrocytic-megaloblastic anemia" by administration of a composition of defined components "to a human in need thereof." The accused product was a dietary supplement having a composition as defined in the claims. It was labeled for uses that did not include treating or preventing macrocytic-megaloblastic anemia. The Federal Circuit found that the claims were limited to the use, as stated in the preamble. Similarly, in *Rapoport v. Dement*, 59 USPQ2d 1215 (Fed. Cir. 2001) a claim directed to "a method for treatment of sleep apneas" was interpreted as being just that, and not a method for treating symptoms associated with sleep apneas, which was found in the art.

In *Jansen* the Federal Circuit observed that

> in both *Rapoport* and this case, the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need.' In both cases, the claims' recitation of a patient or a human 'in need' gives life and meaning to the the preambles' statement of purpose. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method is performed.

Jansen at 1158. In this case, the claim is directed to "a method for reducing angiogenesis in cancerous angiogenesis-related disease" Treatment is given to "cells of the cancer," i.e. to cells of

the cancerous angiogenesis-realted disease Therefore, this recitation is equivalent to the "in need" statements of *Jansen* and *Rapoport*.

In the Advisory Action of April 25, 2006, the Examiner states that she

> acknowledges and agrees with applicant's statement that "simply because reduction of angiogenesis may have occurred does not give rise to a basis for an anticipation rejection under principles of inherency." However, because each of the reference discloses a method performing the active step of the claimed method in a cell that is a target cell of the invention, each of the reference discloses methods that, absent evidence to the contrary, has the effect of reducing angiogenesis.

Applicants submit that this shifting of burden is inappropriate. The burden in the first instance is on the Examiner to show that each and every element of the claimed invention (not just the one active step) is taught by the reference.

Furthermore, the Examiner's argument is inconsistent with established law. In *Merck & Co. Inc. v. Teva Pharmaceuticals USA Inc.*, 68 USPQ2d 1857 (CA FC 2003) a claim to a method of treating a specified condition comprising administering an old compound to a person in need of treatment was found valid over, and not anticipated a prior reference saying the old compound could be used in pharmaceuticals generally because it did not disclose every limitation of the claimed invention.

Applicants further note an earlier case involving a claim to a second medical use. In *In re Marshall*, 198 USPQ 344 (CCPA 1978), the invention dealt with the new pharmaceutical use (weight loss) for a previously known drug which was described in the Physician's Desk reference (PDR). The CCPA reversed the holding of anticipation observing that "if anyone ever lost weight by following the PDR teachings it was an unrecognized accident. An accident or unwitting anticipation of an invention cannot constitute an anticipation." 198 USPQ at 346.

As discussed below with respect to the specific reference cited, there is no teaching that reduction in clusterin levels can result in a reduction in angiogenesis. Thus, the present case is parallel to those in the cited cases, and the anticipation rejections should be reversed.

A. *US Patent No. 6,383,808 of Monia et al.*

Claims 6 and 7 stand rejected as anticipated by Monia et al. US 6,383,808. The Examiner states that Monia et al disclose all limitations of and anticipate claims 6 and 7. However, nowhere in the Official Action does the examiner identify where in Monia there is a disclosure of reducing angiogenesis, and in fact the Examiner has acknowledged that "Monia is silent with regard to reduction of angiogenesis." (Office Action of February 28, 2006, Page 4). Moreover, the Examiner has not shown that any of the cell lines tested in Monia would have any relevance or relationship to angiogenesis. It should further be noted that nothing may be implied from the ability to treat a disease such as glioma (although glioma is only taught as a target by Monia, not as a successful result) concerning the ability to reduce angiogenesis simply because glioma does involve angiogenesis at some stages in its progression. Thus, Monia does not anticipate claims 6 and 7.

B. *US Patent No. 6,900,187 of Gleave et al.*

Claims 6-8 are rejected as anticipated by Gleave '187. As in the case of Monia, there is no reference to angiogenesis in Gleave '187. That the cancer mentioned in Gleave '187 may, at some stages undergo angiogenesis does not mean that angiogenesis would have occurred in the control tests reported in the Gleave '187 patent. Thus, there is no anticipation by Gleave '187.

C. *US Publication 2003/0158130 of Gleave et al.*

Claims 6-8 are rejected as anticipated by Gleave 2003. As in the case of Monia, there is no reference to angiogenesis in Gleave 2003. That the cancer mentioned in Gleave 2003 may, at some stages undergo angiogenesis does not mean that angiogenesis would have occurred in the control tests reported in the Gleave 2003 patent. Thus, there is no anticipation by Gleave 2003.

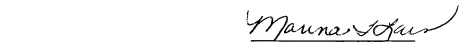
3. *Provisional Obviousness-Type Double-Patenting Rejection*

Claims 6 and 7 are provisionally rejected for obviousness-type double patenting in view of claims 20, 21 and 29 of US Application No. 10/646,436. These claims relate to a method of treating cancer by administration of an RNA molecule that inhibits clusterin expression. As in the case of the anticipation rejections, the Examiner ignores the preamble and considers only the middle of the claim, even though neither the claims nor the '436 application as a whole say anything about angiogenesis. This is improper. The scope of the claims of the two applications must be considered and an assessment of obviousness must be made much as in a 103 rejection, not merely an inquiry into whether there may be some overlap. *Eli Lilly & Co. v. Barr Laboratories Inc.* 55 USPQ 2d 1609 (Fed. Cir. 2000). As stated in *Lilly*, "obviousness-type double patenting entails a two step analysis." 55 USPQ 2d at 1617. The first step is a construction of the claims "to determine whether the later claim encompasses subject matter previously claimed." *Id.* The second step requires a determination "whether the differences in subject matter between the two claims is such that the claims are patentably distinct." The Examiner has performed only the first step of this analysis, and has used the result of this determination as conclusive evidence of the outcome of the second. This is clearly an erroneous application of the doctrine of obviousness type double patenting.

It is further noted that in this case, the substance of the claim that the Examiner is extracting from the cited application is the same as the subject matter extracted from the references. The practical result of this is that the double-patenting rejection would place the present applicants in a worse position than a third party, who could not be subject to this

rejection. This was not the intent when the judicially-created doctrine was created. For these reasons, the provisional obviousness-type double patenting rejection should be reversed.

Respectfully submitted,



Marina T. Larson Ph.D.
PTO Reg. No. 32,038
Attorney for Applicant
(970) 262 1800

Claims Appendix

1-5. (canceled)

6. (rejected) A method for reducing angiogenesis in a cancerous angiogenesis-related disease, comprising treating cells of the cancer with amount of a therapeutic oligonucleotide composition effective to reduce the effective amount of clusterin in the cells, and thereby to reduce the occurrence of angiogenesis.

7. (rejected) The method of claim 6, wherein the therapeutic oligonucleotide composition comprises an antisense oligonucleotide complementary to the sequence of human clusterin (Seq. ID. No. 1).

8. (rejected) The method of claim 7, wherein the antisense oligonucleotide is selected from the group consisting of oligonucleotides whose sequence consists essentially of a sequence as set forth in Seq. ID Nos. 2- 15.

9. (withdrawn) The method of claim 6, wherein the therapeutic oligonucleotide composition comprises an RNAi agent.

10. (withdrawn) The method of claim 9, wherein the RNAi agent is selected from the group consisting of oligonucleotides whose sequence consists essentially of a sequence as set forth in Seq. ID Nos. 16 to 23 or a sequence complementary thereto.

Evidence Appendix

None

Related Proceedings Appendix

Decision on Appeal 2005-2447 (Serial No. 09/619,908)

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARTIN GLEAVE and HIDEAKI MIYAKE

Appeal No. 2005-2447
Application No. 09/619,908

HEARD: October 18, 2005

Before SCHEINER, ADAMS and MILLS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1-23 and 26-40. Claims 24 and 25, also pending in the application, have been allowed.

BACKGROUND

> Insulin-like growth factor (IGF)-I and IGF-II are potent mitogens for many normal and malignant cells. Accumulating evidence suggests that IGFs play an important role in the pathophysiology of prostatic disease and breast cancer. . . .
>
> The biological response to [IGFs] is regulated by various factors, including IGFBPs [(insulin-like growth factor binding proteins)]. To date, six IGFBPs have been identified whose function is believed to involve modulation of the biological actions of the IGFs through high affinity interactions . . . However, some evidence suggests biological activity for IGFBPs that are independent of IGFs, . . . and both stimulatory and inhibitory effects of IGFBPs on cell proliferation have been reported under various experimental conditions. . . .

Specification, pages 1-2.

"[P]rostate cancer is an androgen-sensitive tumor, [thus,] androgen withdrawal . . . is utilized in some therapeutic regimens . . . [and] leads to extensive apoptosis in the prostate tumor, and hence to a regression of the disease. However, . . . apoptosis is not complete, and a progression of surviving tumor cells to androgen-independence ultimately occurs." Id., page 1. The present invention is concerned with delaying the ultimate progression of tumor cells to androgen-independence.

Appellants "initially characterized the changes [in] IGFBPs expression in the Shionogi tumor model[1] after castration and during [progression to androgen-independence]" (Specification, page 5). "Of the IGBFPs expressed in Shionogi tumors, the most dramatic changes in expression were observed with IGFBP-5. Despite undetectable levels in [androgen-dependent] intact tumors, IGFBP-5 expression is highly upregulated after castration, and remains highly expressed in [androgen-independent] tumors." Id., pages 5-6. Moreover, "[t]he pattern of

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[1] "The Shionogi tumor model is a xenograft of an androgen-dependent mouse mammary carcinoma that grows subcutaneously in male syngenic hosts." Specification, pages 4-5. Shionogi tumor cells "are highly tumorigenic and locally invasive . . . [and] have been shown to respond to androgen withdrawal in a manner which mimics the observed behavior of prostatic tumor cells," that is, "androgen withdrawal precipitates apoptosis and tumor regression in a highly reproducible manner" (id., page 5). "Further, changes in expression of peptides . . . in human prostate cancer following castration and during progression to androgen-independence are similar to those observed in Shionogi tumor cells. Because of these similarities, the Shionogi tumor model mimics human prostate cancer and provides a very useful model for the evaluation of the ability of compounds to delay the onset of androgen-independence. Despite complete tumor regression after castration, rapidly growing androgen-independent Shionogi tumors invariably recur after one month, which provides a reliable end point to evaluate agents which can delay the progression to androgen-independence." Id.

IGFBP-5 upregulation in the Shionogi tumor model during [progression to androgen-independence] . . . is similar to that in rat prostate . . . and human prostate" (id., page 6).

According to appellants, antisense oligodeoxynucleotides (ODNs) complementary to portions of the gene encoding IGFBP-5 "inhibit[ ] cell proliferation and induce[ ] cell cycle arrest in Shionogi tumor cells in a time- and dose-dependent manner . . . [and do] not appear to induce apoptosis either in vitro or in vivo, . . . suggest[ing] that antisense IGFBP-5 activity occurs via inhibition of cell proliferation rather than induction of apoptosis." Id. Appellants "hypothesized that targeting upregulation precipitated by androgen using [an] antisense strategy might inhibit progression to androgen-independence." Id., page 7. In appellants' "in vivo experiments, administration of antisense IGFBP-5 after castration delayed time to [androgen-independence] . . . and inhibited [androgen-independent] recurrent tumor growth." Id.

THE CLAIMS

The present invention is directed to "a method for delaying the progression of hormone-regulated (prostatic or breast) tumor cells to hormone (e.g. androgen or estrogen) independence, a therapeutic method for the treatment of individuals . . . suffering from hormone regulated cancers, such as breast or prostate cancer, and therapeutic agents effective for use in such methods." Specification, page 4. In addition, the present invention is directed to a method of inhibiting or delaying metastatic boney progression of an IGF-1 sensitive tumor in a mammal. We note that the claims on appeal require an antisense oligonucleotide that inhibits expression of

IGFBP-5, with the exception of method claims 8, 12, 15, 19, 39 and 40, which merely require "a composition effective to inhibit expression of IGFBP-5."

Claims 1, 8, 15 and 22 are representative of the subject matter on appeal:

1. A method for delaying progression of hormone-regulated mammalian tumor cells to an androgen-independent state, comprising treating hormone-sensitive mammalian tumor cells with an antisense oligonucleotide which inhibits expression of IGFBP-5 by the tumor cells.

8. A method for treating a hormone-responsive cancer in a mammalian individual suffering from hormone-responsive cancer, comprising the steps of initiating hormone-withdrawal to induce apoptotic cell death of hormone-responsive cancer cells in the individual, and administering to the individual a composition effective to inhibit expression of IGFBP-5 by the hormone-responsive cancer cells, thereby delaying the progression of hormone-responsive cancer cells to a hormone-independent state in the individual.

15. A method for inhibiting or delaying metastatic boney progression of an IGF-1 sensitive tumor in a mammal, comprising the step of administering to the mammal a composition effective to inhibit expression of IGFBP-5 by the hormone-responsive cancer cells, thereby inhibiting or delaying metastatic boney progression of the tumor.

22. A composition for treatment of hormone-regulated cancer comprising an antisense oligonucleotide which inhibits expression of IGFBP-5 by hormone-regulated tumor cells.

THE REJECTIONS

The claims stand rejected as follows:

I. Claims 1, 5, 22 and 36-38[2] under 35 U.S.C. § 102 (b) as anticipated by Huynh.[3]

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[2] Claims 36-38 were subject to this ground of rejection in the final rejection (paper no. 14, January 24, 2003), but were omitted from the examiner's statement of the rejection in the Answer. The omission of these claims appears to have been a typographical error, as they are specifically discussed in the examiner's response to appellants' arguments (see, e.g., page 16 of the Answer).

[3] Huynh et al., "A Role for Insulin-like Growth Factor Binding Protein 5 in the Antiproliferative Action of the Antiestrogen ICI 182780," Cell Growth & Differentiation, Vol. 7, pp. 1501-1506 (November 1996)

II. Claims 1-3, 5, 6, 22, 23, 26-28, and 36-38[4] under 35 U.S.C. § 103 (a) as unpatentable over Huynh in view of Kiefer,[5] Baracchini[6] and Nickerson.[7]

III. Claims 1-3, 4, 6, 8-10, 12, 13, 15-17, 19, 20, 22, 23 and 38-40 under the first paragraph of 35 U.S.C. § 112, written description.

IV. Claims 1-23 and 26-40 under the first paragraph of 35 U.S.C. § 112, enablement.

DISCUSSION

I. Anticipation

Claims 1, 5, 22 and 36-38 stand rejected under 35 U.S.C. § 102 (b) as anticipated by Huynh. Claims 1, 5 and 38 are method claims, while claims 22, 36 and 37 are composition claims. Appellants argue that the method and composition claims do not stand or fall together because "anticipation of a method claim requires a different content of the reference than a composition claim, which need only disclose the same composition, rather than the same method steps." Brief, page 3. Accordingly, we will consider claim 1 to be representative of the method claims, and claim 22 to be representative of the composition claims – claims 5 and 38 will stand or fall with claim 1, while claims 36 and 37 will stand or fall with claim 22.

Claim 1 is directed to a method of delaying progression of hormone-regulated

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[4] Claim 40 was included in this rejection in the final rejection, but the rejection was withdrawn with respect to claim 40 in the Examiner's Answer (page 17).

[5] Kiefer et al., "Molecular Cloning of a New Human Insulin-like Growth Factor Binding Protein," Biochem. Biophys. Res. Commun., Vol. 176, No. 1, pp. 219-225 (1991).

[6] U.S. Patent No. 5,801,154, issued to Baracchini et al. on September 1, 1998.

[7] Nickerson et al., "Castration-Induced Apoptosis in the Rat Ventral Prostate is Associated with Increased Expression of Genes Encoding Insulin-Like Growth Factor Binding Proteins 2, 3, 4 and 5," Endocrinology, Vol. 139, No. 2, pp. 807-810 (1998).

mammalian tumor cells to an androgen-independent state by treating the cells with an antisense oligonucleotide which inhibits expression of IGFBP-5 by the tumor cells. According to the examiner, "a key limitation is that the method steps are carried out in hormone sensitive mammalian tumor cells" (Answer, page 14), and "Huynh discloses administering an antisense oligomer comprising 21 nucleotides targeted to IGFBP-5 to breast cancer cells" (id., page 5). The examiner acknowledges that Huynh says nothing about delaying progression of hormone-regulated mammalian tumor cells to an androgen-independent state, but argues that "any recited outcome such as that is merely considered to be an inherent feature, since all the structural and manipulative features of the claim are present in Huynh" (id.).

It is well settled that a prior art reference may anticipate even when claim limitations are not expressly found in that reference, but are nonetheless inherent in it. See, e.g., Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999); Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). However, it is also the case that "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Here, Huynh teaches that "IGFBP-5 can either stimulate or inhibit cellular proliferation in different experimental systems . . . suggest[ing] that there are poorly characterized complexities in IGFBP-5 action" (Huynh, pages 1503-1504). Indeed, on this record, there is no dispute that "Huynh [ ] actually teach[es] that antisense to IGFBP-5 stimulates cell proliferation in the [MCF-7] breast cancer cell line used" (Answer, page 14), while it inhibits proliferation in the Shionogi tumor cells used by

appellants. According to the examiner, this variation in the effects of antisense IGFBP-5 is irrelevant "because cellular proliferation (or inhibition thereof) is not recited as a claim limitation" (id.). In our view, however, this variation is relevant because it shows that in the only directly comparable parameter of record, the two cell lines react differently to inhibition of IGFBP-5. While Huynh says nothing about delayed progression to androgen-independence, it is not unreasonable to expect that the two cell lines might react differently to inhibition of IGFBP-5 in this respect as well, especially in light of Huynh's suggestion that the actions of IGFBP-5 are poorly characterized. In our view, the examiner has established that inhibition of IGFBP-5 in Huynh's MCF-7 cells might delay progression to androgen-independence, but has not established that it will. As discussed above, this is not sufficient to establish a prima facie case of anticipation based on inherency.

Accordingly, the rejection of claims 1, 5 and 38 as anticipated by Huynh is reversed.

Claim 22, however, stands on a different footing. Claim 22 is directed to "a composition for treatment of hormone-regulated cancer comprising an antisense oligonucleotide which inhibits expression of IGFBP-5 by hormone-regulated tumor cells." Huynh plainly describes an IGFBP-5 antisense oligodeoxynucleotide which reduces expression of IGFBP-5 in human breast cancer cells. Appellants argue that "the phrase 'for treatment of hormone-regulated cancer' is more than a statement of intended use and deserves to be given weight in assessing the scope of the claims." Brief, page 7. According to appellants, "Huhnh's antisense is not used in the treatment of any animal or human . . . [thus,] [t]here is no teaching of a composition suitable for

administration in the treatment of cancer." Id. Nevertheless, appellants have not pointed out anything which makes Huynh's IGFBP-5 antisense oligonucleotide composition unsuitable for administration to an animal, or which distinguishes it from the claimed IGFBP-5 antisense oligonucleotide composition in any way.

Accordingly, the rejection of claim 1 as anticipated by Huynh is affirmed. As discussed above, claims 36 and 37 stand or fall with claim 22, thus the rejection of claims 36 and 36 as anticipated by Huynh is affirmed as well.

II. Obviousness

Claims 1-3, 5, 6, 22, 23, 26-28, and 36-38 stand rejected under 35 U.S.C. § 103 (a) as unpatentable over Huynh in view of Kiefer, Baracchini and Nickerson. Having already determined that Huynh anticipates the subject matter of claims 22, 36 and 37, we affirm the rejection under 35 U.S.C. § 103 (a) with respect to those claims. "[A]nticipation is the epitome of obviousness." Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

Claims 1-3, 5, 6, 23, 26-28 and 38, on the other hand, are directed to methods of delaying the progression of hormone-regulated tumor cells to an androgen-independent state; to treating a hormone-responsive cancer; and to delaying metastatic boney progression of IGF-1 sensitive tumors by inhibiting IGFBP-5.

The examiner relies on Huynh for disclosure of "an antisense oligomer comprising 21 nucleotides targeted to IGFBP-5 that was administered to breast cancer cells" (Answer, page 6); on Kiefer for disclosure of the translation initiation and termination regions of IGFBP-5 (id.); and on Baracchini for "teach[ing] that the translation initiation and termination regions are preferred regions for targeting with

antisense oligos" (id.). According to the examiner, these references provide motivation for targeting particular regions of IGFBP-5 in order to inhibit its effects. Id., pages 6-7.

Nevertheless, in our view, the dispositive issue here is the examiner's proposed rationale for inhibiting IGFBP-5 in tumor cells in the first place. The underlying premise of the examiner's rejection is that "Nickerson teaches that prostatic tumor cells over-express IGFBP-5 and [that IGFBP-5] is involved in tumorigenesis" (id., page 6), and that, therefore, it would have been obvious for one skilled in the art to inhibit IGFBP-5 expression in prostatic tumor cells (id., page 7).

We see no factual basis for the examiner's expansive interpretation of Nickerson's teachings. Nickerson's experiments were designed "to study the gene expression of IGFBPs during involution of the rat ventral prostate after castration." Nickerson, page 807. The experiments demonstrated that "IGFBP-5 mRNA increases in the ventral prostate 2-fold by 24 h and 5-fold by 72 h [ ] in keeping with the hypothesis that IGFBP-5 may be involved in apoptosis resulting from steroid hormone deprivation." Id., page 809, left-hand column. According to Nickerson, the experimental system could not determine "whether IGFBPs cause apoptosis in the ventral prostate or are upregulated as a result of apoptosis." Id., right-hand column. Either way, the examiner has not explained how Nickerson's observations suggest that IGFBP-5 is involved in tumorigenesis, or why one skilled in the art would have wanted to inhibit its effects.

The examiner bears the initial burden of establishing prima facie obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a prima facie conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See In re Lowry, 32 F.3d 1579, 1582, 32

USPQ2d 1031, 1034 (Fed. Cir. 1994). In addition, the record must provide evidence that those of skill in the art would have had a reasonable expectation of success in doing so. See In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

We agree with appellants that the examiner's rejection "fails to state a prima facie case of obviousness." Brief, page 8. The rejection of claims 1-3, 5, 6, 23, 26-28 and 38 under 35 U.S.C. § 103 is reversed.

III. Written Description

Claims 1-3, 4, 6, 8-10, 12, 13, 15-17, 19, 20, 22, 23 and 38-40 stand rejected under the first paragraph of 35 U.S.C. § 112, as lacking adequate written descriptive support.

"The 'written description' requirement serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted). Another "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69

USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116), and it is the examiner's "initial burden [to] present[ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)).

With respect to claims 1-3, 4, 6, 9, 10, 13, 16, 17, 20, 22, 23 and 38, we disagree with the examiner's rationale and conclusion. These claims require antisense oligonucleotides, of varying scope, which inhibit expression of IGFBP-5 in hormone-regulated mammalian tumor cells. The examiner argues that "[t]he specification . . . only describes two target IGFBP-5 sequences, [mouse and human] . . . , and does not describe any additional sequences that can be targeted via antisense oligos. Without such a description, the skilled artisan would not be able to envision any other target sequences and thus would not be able to synthesize an antisense oligo specific for the sequence" (Answer, page 8), and moreover, would be "required to undertake de novo experimentation to isolate and identify IGFBP-5 encoding nucleic acids" (id.).

Nevertheless, "applicants have some flexibility in the 'mode selected for compliance' with the written description requirement" (University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896), and it is well settled that actual reduction to practice is not necessary to satisfy the requirement (id. at 926, 69 USPQ2d at 1894). On the other hand, "[i]n claims to genetic material . . . [a] definition by function . . . does not suffice to to define [a] genus because it is only an indication of what the [material] does, rather than what it is." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court explained that "[a]n adequate written

description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,'" (id. at 1566, 43 USPQ2d at 1404) while "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" (id. at 1568, 43 USPQ2d at 1406). Subsequently, the court clarified that "the written description requirement would be met for [a claim] . . . if [a] functional characteristic . . . were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." Enzo Biochem, 296 F.3d at 1324-25, 63 USPQ2d at 1613.

Here, the specification sets forth the sequences of DNA molecules encoding the mouse and human IGFBP-5s, as well as a number of antisense sequences targeting specific regions of the mouse and human IGFBP-5 DNAs. The examiner's rationale would seem to limit the claimed genus to only those antisense oligonucleotides explicitly recited, without explaining why one skilled in the art would not have expected the mouse and human DNAs to be representative of, or have considerable structural similarity to, DNA encoding IGFBP-5 in other mammals. Again, it is the examiner's "initial burden [to] present[ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (Wertheim, 541 F.2d at 263, 191 USPQ at 97). We find that the examiner has not done so.

Accordingly, the rejection of claims 1-3, 4, 6, 9, 10, 13, 16, 17, 20, 22, 23 and 38 as lacking adequate written descriptive support under 35 U.S.C. § 112, first paragraph, is reversed.

With respect to claims 8, 12, 15, 19, 39 and 40, however, we agree with the examiner that adequate written descriptive support is lacking. We note that these claims merely require "a composition" effective to inhibit expression of IGFBP-5. The only such compositions disclosed in the specification are the afore mentioned antisense oligonucleotides. The examiner's position is essentially that the specification does not provide "any description, structural[ ] or otherwise, of IGFBP-5 inhibitors other than the instantly described antisense oligo[nucleotides]" and that the instantly described antisense oligonucleotides are "not representative of the breadth of inhibitors sought in the instant claims" (Answer, page 8).

Appellants argue that "the invention is based on the discovery . . . that reducing the expression of IGFBP-5 in hormone-responsive cancer cells has therapeutic benefits" (Brief, page 12), and "antisense inhibitors of IGFBP-5 expression [are] examples of a methodology that can be used in practicing the methods" (id., page 13). Appellants argue that the invention "is not antisense technology per se. It is also not the identification of IGFBP-5, nor any and all inhibitors of IGFBP-5 expression" (id., page 12).

These arguments are not persuasive. The Federal Circuit has recently held that the written description standard discussed in Eli Lilly applies to methods as well as products. See University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 926, 69 USPQ2d 1886, 1894 (Fed. Cir. 2004): "Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods."

The facts in Rochester are similar to those of the instant application. Rochester involved a "method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment." Id. at 920, 69 USPQ2d at 1888 (emphasis added). The court noted that the relevant patent described the cells needed to screen for compounds having the recited property, as well as "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product." Id. At 927, 69 USPQ2d at 1895. Nevertheless, the court concluded that the patent's disclosure was inadequate to enable the claimed method because the patent "[did] not disclose just which peptides, polynucleotides, and small organic molecules have the desired characteristic of selectively inhibiting PGHS-2." Id. (emphasis in original, internal quotations omitted). "Without such disclosure, the claimed methods cannot be said to have been described." Id.

In this case, as in Rochester, the claims are directed to a process for accomplishing a desired result (in Rochester, selectively inhibiting PGHS-2 activity in a human host; here, "inhibiting expression of IGFBP-5 in hormone-responsive cells") using a composition having a specified functional property (in Rochester, a "non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product"; here, "a composition effective to inhibit expression of IGFBP-5"). And in this case, as in Rochester, the specification provides no description whatsoever of just which compositions have the functional property recited in the claims - the genus recited in the claims is defined exclusively in functional terms, i.e., in terms of what the members of the genus do, rather than what they are.

As discussed above, "[a] definition by function . . . does not suffice to define [a] genus because it is only an indication of what the [material] does, rather than what it is." Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. To paraphrase Eli Lilly, naming a type of material, which may or may not exist, in the absence of knowledge as to what that material consists of, is not a description of that material. See id. Accordingly, the rejection of claims 8, 12, 15, 19, 39 and 40 as lacking adequate written descriptive support under 35 U.S.C. § 112, first paragraph, is affirmed.

IV. Enablement

Claims 1-23 and 26-40, all the claims on appeal, stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement. According to the examiner, the claims are drawn to "antisense oligo[nucleotides] targeted to any transcript of IGFBP-5 as well as methods of treatment using said antisense oligo[nucleotides]" (Answer, page 9), but the specification "is only enabling for antisense oligos of SEQ ID NO:1 targeted to the IGFBP-5 transcripts of [murine] SEQ ID NO:13, and for the use of SEQ ID NOS; 2, 3 and 9 in the inhibition of SEQ ID NO:14 in vitro, and does not provide guidance on the in vivo inhibition of [human] SEQ ID NO:14" (id.).

With respect to claims 1-7, 9-11, 13, 14, 16-18, 20-23 and 26-48, all of which require an antisense oligonucleotide capable of inhibiting expression of IGFBP-5, we do not agree with the examiner's rationale or conclusion, for the reasons that follow. Initially, however, we note that the examiner has focused exclusively on the therapeutic use of antisense oligonucleotides, and has not separately addressed the enablement of those claims that do not require antisense oligonucleotides (as was done in the written description rejection above). Nevertheless, our affirmance of the written description rejection for claims 8, 12, 15, 19, 39 and 40 constitutes a disposition of these broader

claims, so we need not reach the merits of the enablement rejection with respect to these claims.

Returning to claims 1-7, 9-11, 13, 14, 16-18, 20-23 and 26-48, then, we find that the reasons cited in support of the examiner's rejection are insufficient to support the examiner's conclusion that these claims are not enabled by the specification.

"The first paragraph of 35 U.S.C. § 112 requires, inter alia, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention. Although the statute does not say so, enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).[8] That some experimentation may be required is not fatal; the issue is whether the amount of experimentation is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (emphasis in original). Nevertheless, "[w]hen rejecting a claim under the enablement requirement of section 112," it is well settled that "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes,

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> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims (footnote omitted).
>
> In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

According to the examiner, "the clinical application of antisense therapy is a highly unpredictable art due to obstacles that still face antisense therapy" (Answer, page 9). The obstacles enumerated by the examiner are essentially: the identification of an appropriate target in the disease process; the identification of a molecule that can interfere with the disease process through specific recognition and affinity; the complexity of cellular uptake of oligonucleotides; and physical barriers due to internal structures of target RNAs and associations with cellular proteins. Id., pages 9-10. In addition, the examiner relies on Gewirtz[9] and Branch[10] as evidence that "'the antisense approach has generated controversy [among those of skill in the art] with regard to mechanism of action, reliability, and ultimate therapeutic utility'" (id., page 10), and the sense in the art is that "'efforts should be increased . . . to learn how they may be used successfully in the clinic'" (id.).

We have no reason to doubt the examiner's assessment of the state of the art in general, and we think it is fair to say that the field of antisense therapy is indeed recognized as highly unpredictable by those of skill in the art. Nevertheless, appellants point out, and the examiner appears to acknowledge, that appellants have identified the murine and human IGFBP-5s as appropriate targets in treating androgen-dependent cancers like prostate cancer and breast cancer, and that appellants have identified

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[9] Giwirtz et al., "Facilitating Oligonucleotide Delivery: Helping Antisense Deliver on Its Promise," Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 3161-3163 (April, 1996).

[10] Branch, A.D., "A Good Antisense Molecule is Hard to Find," TIBS, Vol. 23, pp. 50 (February, 1998).

antisense IGFBP-5 molecules that can delay progression to androgen independence in the Shionogi tumor model (asserted to be a useful model of human prostate cancer) and/or inhibit expression of IGFBP-5 in human prostate cancer cell lines. See page 17 of the substitute Brief for Appellant (submitted June 10, 2004), and page 9 of the Answer. This concrete guidance, in the form of working examples, would seem to address a number of the examiner's specific concerns, and weigh in favor of finding the specification enabling for claims directed to antisense inhibition of IGFBP-5. In any case, the examiner has not explained why the specific guidance in the specification would not, at least to some extent, mitigate or counterbalance any remaining factors (e.g., the generally unpredictable nature of the field) tending to weigh against a finding of enablement. In other words, the examiner has not explained why identifying other antisense IGFBP-5 molecules capable of delaying progression of hormone-regulated tumor cells to androgen-independence, either in vivo or in vitro would have required undue experimentation, given the specific guidance provided by appellants in their working examples.

Accordingly, the rejection of claims 1-7, 9-11, 13, 14, 16-18, 20-23 and 26-48 as lacking enablement under the first paragraph of 35 U.S.C. § 112 is reversed.

SUMMARY

I. The rejection of the claims under 35 U.S.C. § 102 (b) as anticipated by Huynh is affirmed with respect to claims 22, 36 and 37, and reversed with respect to claims 1, 5 and 38.

II. The rejection of the claims under 35 U.S.C. § 103 (a) as unpatentable over Huynh, Kiefer, Baracchini and Nickerson is affirmed with respect to claims 22, 36 and 37, and reversed with respect to claims 1-3, 5, 6, 23, 26-28 and 38.

III. The rejection of the claims under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support is affirmed with respect to claims 8, 12, 15, 19, 39 and 40, and reversed with respect to claims 1-3, 4, 6, 9, 10, 13, 16, 17, 20, 22, 23 and 38.

IV. The rejection of the claims under 35 U.S.C. § 112, first paragraph, as lacking enablement is reversed with respect to claims 1-7, 9-11, 13, 14, 16-18, 20-23 and 26-48. We do not reach the merits of this rejection with respect to claims 8, 12, 15, 19, 39 and 40.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136 (a).

AFFIRMED-IN-PART

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

Oppedahl and Larson LLP
PO Box 5068
Dillon CO 80435-5068